

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*West Boca Medical Center, Inc. v.
AmerisourceBergen Drug Corp., et al.,*
No. 18-op-45530

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF THE MANUFACTURER DEFENDANTS'
JOINT MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

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INTRODUCTION

The Opposition filed by West Boca Medical Center, Inc. (“Hospital” or “Plaintiff”) makes clear that all of its claims are barred by controlling law. The Hospital concedes that courts across the country have dismissed with prejudice virtually identical claims for the recovery of unreimbursed medical expenses brought by hospitals against tobacco companies for lack of causation, because the claims were too attenuated and merely derivative of the injuries to consumers who experienced tobacco-related illnesses. The Sixth Circuit has expressly approved and relied upon these decisions in affirming the dismissal of similar RICO and state law claims, agreeing that the “alleged injuries are too remote.” *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849-50 (6th Cir. 2003).

The Hospital spends much of its Opposition trying to distinguish this controlling decision (and others) by arguing that, unlike cigarettes, doctors must prescribe the Manufacturer Defendants’ opioid medicines. This distinction, however, only underscores that the chain of causation is ***even more attenuated***, because doctors have an independent legal obligation to know and weigh the risks of the opioid medicines they prescribe. Even the Hospital concedes that its chain of causation rests upon numerous additional intervening actions, including the criminal conduct of third-party “pill seekers,” the Hospital’s decision to dispense opioid medications to patients, and the patient’s decision-making and financial ability to pay for medical care.

Beyond that, despite filing a 70-page Opposition, the Hospital fails to identify a ***single*** allegedly false or misleading statement made to the Hospital or any doctor who wrote an opioid prescription at issue; a ***single*** opioid prescription that was written because of an allegedly false statement or omission by any Defendant, much less one that did not provide effective pain relief, and caused the Hospital some harm; or a ***single*** opioid-related unreimbursed medical expense linked to a misrepresentation, omission, or misconduct by one of the Manufacturer Defendants.

These are not superfluous details; they are the very core of the Hospital’s legal theory. Despite proclaiming to be “uniquely” situated, Opp. 4, the Hospital throughout its Opposition relies on the same deficient legal theories municipal plaintiffs (like Summit and Broward Counties) invoked in other cases. Because the Hospital’s claims fail as a matter of law and the Hospital cannot cure its pleading deficiencies, the Complaint should be dismissed with prejudice.¹

ARGUMENT

I. THE HOSPITAL CANNOT ESCAPE CONTROLLING SIXTH CIRCUIT PRECEDENT AND NUMEROUS OTHER CASES THAT HAVE DISMISSED CLAIMS AGAINST PRODUCT MANUFACTURERS BROUGHT BY HOSPITALS SEEKING TO RECOVER UNREIMBURSED EXPENSES.

The Hospital concedes that the Sixth Circuit and other courts have rejected RICO and state law claims against tobacco manufacturers to recover healthcare expenses associated with treating alleged smoking-related injuries to patients. Opp. 4, 19; *see Perry*, 324 F.3d at 849. Many of these cases were brought by hospitals, yet the courts uniformly recognize that “[n]o amount of semantic gymnastics can detract from the conclusion that [plaintiffs’] claims are completely derivative of the personal injuries to [smokers] allegedly caused by the defendants’ conduct.” *Ass’n of Wash. Pub. Hosp. Districts v. Philip Morris Inc.*, 79 F. Supp. 2d 1219, 1225 (W.D. Wa. 1999), *aff’d*, 241 F.3d 696, 704 (9th Cir. 2001); *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 444 (3d Cir. 2000) (same).

Like those cases, the Hospital’s alleged harm—the unpaid costs of treating opioid users with medical conditions necessitating hospitalization (Opp. 1)—is far removed from any allegedly

¹ Unless otherwise noted, all capitalized terms and acronyms are defined in the Memorandum In Support Of The Manufacturer Defendants’ Joint Motion To Dismiss Plaintiffs’ Complaint (Dkt. #691-1) (“Motion” or “JM”). In addition, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted. “Opposition” or “Opp.” refers to Plaintiffs’ Omnibus Memorandum In Opposition (Dkt. #806).

false marketing or advertising by the Manufacturer Defendants and is “inherently contingent on injury to third-party” users of opioid medications. *Perry*, 324 F.3d at 849. The Hospital’s RICO and state law claims therefore fail under controlling Sixth Circuit law and other well-established principles of proximate cause, particularly given that “remoteness principles are not limited to cases involving the RICO statute” and state law claims also impose a “direct injury” requirement. *Id.* at 850.

The Hospital goes to great lengths to try to distinguish these controlling cases, but its “semantic gymnastics” do not rescue its claims. Opp. 19–21. Virtually all of the Hospital’s purported distinctions rest on the facts that opioid medications “treat disease,” are heavily regulated as part of a “comprehensive federal licensing” and “registration and reporting system,” and can be distributed only through a chain involving physicians, hospitals, and pharmacies. *Id.* But the independent decision-making of these sophisticated and highly-trained actors adds ***even more links*** in the already attenuated proximate causation chain—and thus make the Hospital’s claims even more indirect. Unlike cigarettes, the FDA-approved opioid medications at issue here serve a legitimate medical purpose and are lawfully obtained only from licensed entities who have the legal obligation to know and “weigh[] the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient’s needs.” *Felix v. Hoffman-LaRoche, Inc*, 540 So. 2d 102, 104 (Fla. 1989). This independent decision-making further breaks the alleged causal chain. *See Holmes v. Sec. Inv’r Prot. Corp.*, 503 U.S. 258, 265-66 (1992); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017).

The Hospital also argues that, unlike the tobacco industry, various governmental actions have been brought against the opioid industry. Opp. 20 (bullet 6). Even if this were a valid distinction (and it is not), it is irrelevant. Governmental actions do not create a direct harm ***to the***

Hospital or do anything to “change the analysis.” *Allegheny Gen. Hosp.*, 228 F.3d at 443. The Hospital’s claims all undisputedly result from harm suffered by third-party users who seek treatment at the Hospital. Under *Perry* and controlling precedent, these claims fail.

Nor can the Court ignore *Perry* and the other tobacco cases on the ground that, unlike those cases, damages are easy to ascertain. To determine the cause of any unreimbursed medical expense, it would be necessary to make a myriad of unworkable individualized inquiries into the conduct of prescribers, patients, and the Hospital itself, including why the patient sought medical attention at the Hospital; if it was due to an opioid-related condition, whether that condition was the result of proper usage of lawful opioid prescriptions, as opposed to other independent factors, such as illicit drug use; and, if a lawful opioid prescription was involved at some point, who dispensed that medicine, for what reason, and whether any allegedly false statement by the Manufacturer Defendants caused the prescription to be written, as opposed to the prescriber’s own independent medical judgment. Critically, the Hospital does not identify a way of ascertaining the damages, if any, traceable to some alleged remote misconduct by the Manufacturer Defendants, thereby further highlighting the lack of any direct injury. *See, e.g., Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458-59 (2006) (applying rule to affirm dismissal of RICO claims). As the Third Circuit has recognized in rejecting similar claims, “the Hospital’s injuries are indirect. Neither the duty to provide medical care, nor the direct or free provision of medical care, affects this conclusion.” *Allegheny Gen. Hosp.*, 228 F.3d at 444 (applying rule).

II. THE “FALSE NARRATIVE ENTERPRISE” RICO CLAIM FAILS (COUNT 1).

The Hospital has not stated a RICO claim because it has not alleged a direct injury, causation, an enterprise, or any predicate act with particularity. *See JM 4-6.* The Hospital simply relies on *Summit County*’s unavailing arguments as to why it has pleaded an enterprise and

predicate acts, *see* Opp. 21, 23, which thus fail for the same reasons as in that case. *Summit* MTD 9-27; *Summit* Reply 6-10, 14-21. Its additional arguments as to a direct RICO injury and causation are meritless too.

Direct Injury. The Hospital’s alleged business injuries are too indirect to support a RICO claim and are entirely derivative of others’ injuries. JM 4-5. In response to *Perry, Allegheny County*, and other controlling cases, the Hospital cites a string of inapposite cases in which district courts allowed RICO claims brought by insurance companies to proceed under an entirely different theory. *See* Opp. 9-10 & n.19. In *every single one* of those cases, the plaintiff insurer was suing for *falsified claims* submitted directly to it—that is, claims for goods or services that either were never provided or that were entirely unnecessary. *E.g., State Farm Mut. Auto. Ins. Co. v. Vital Cnty. Care, P.C.*, 2018 WL 2194019, at *1 (E.D. Mich. May 14, 2018) (“fraudulent bills and false documentation for treatment and services that were never performed or were not medically necessary”); *State Farm Mut. Auto. Ins. Co. v. Universal Health Grp., Inc.*, 2014 WL 5427170, at *3 (E.D. Mich. Oct. 24, 2014) (“fraudulent initial diagnoses … fraudulent examinations which lead to the prescription of unnecessary treatments … fraudulen[t] … EDX tests” and “fraudulen[t] … MRIs”); *State Farm Mut. Auto. Ins. Co. v. Physiomatrix, Inc.*, 2014 WL 555199, at *1 (E.D. Mich. Feb. 12, 2014) (“submission of fraudulent claims for physical therapy services that were not medically necessary or not performed.”).

Unlike the plaintiffs in those cases, the Hospital *does not allege* that it paid falsified claims for medications not received or incurred expenses for medically unnecessary treatment. Surely it would have if it could; records of the Hospital’s purchases and expenditures are solely within its possession and control. Regardless, the Hospital’s reliance on insurance cases simply underscores the indirect nature of its *actual* legal theory in this litigation: the recovery of costs for “its treatment

of patients with opioid conditions” (Compl. ¶ 55), which is “inherently contingent on injury to third part[ies].” *Perry*, 324 F.3d at 849; *accord Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013).

Causation. The Hospital has not established but-for or proximate causation. JM 4-5; *Summit* Reply 6-10. The Opposition does not identify a single prescriber (either affiliated with the Hospital or not) who received and relied upon an alleged misrepresentation or omission from any of the Manufacturer Defendants—much less a prescriber who wrote a medically unnecessary prescription to a patient who sought treatment at the Hospital and was unable to pay his or her bills. This alone defeats but-for causation. *Id.*; *see also Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App’x 82, 87 (3d Cir. 2015).

Similarly, the Opposition confirms that the Hospital **cannot** establish proximate causation as a matter of law. The Hospital claims that Manufacturer Defendants’ actions “have impaired the hospitals’ ability to perform their integral responsibilities to patients,” including because they “can no longer trust patients to self-report their prescriptions.” Opp. 15. It is hard to imagine a more remote causal chain. Indeed, there is no link between the marketing of FDA-approved prescription opioid medications, on the one hand, and patients who refuse to tell their doctors whether they currently have a lawful prescription for opioid medications, on the other. Worse yet, the Hospital makes clear that its own decision-making serves as an intervening event, including its ability to “properly limit [its] purchasing and dispensing of opioids,” which is **entirely** within its own control. Opp. 15. And the Hospital acknowledges that its claims hinge upon “***an opioid victim’s inability to pay***” for medical care—yet another individualized and independent factor. Opp. 18.

The Hospital argues that all of these independent actions and events were foreseeable to the Manufacturer Defendants. Opp. 13-19. But the Hospital alleges no facts to show how, for

instance, a patient’s ability to pay for hospital care or to self-report prescriptions would be foreseeable to manufacturers of opioid medicines. Nor is foreseeability the sole factor for proximate causation under RICO or common-law principles, as the Supreme Court has made clear. *See, e.g., Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1305-06 (2017) (rejecting foreseeability test and requiring “some direct relation between the injury asserted and the injurious conduct alleged” based on common-law principles); *Hemi Grp., LLC v. City of New York, N.Y.*, 559 U.S. 1, 12 (2010) (plurality concluding the same for RICO claims). Nonetheless, in an attempt to save its defective claims, the Hospital invokes the First Circuit’s opinion in *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). Opp. 6, 12, 16, 18. This reliance is misplaced for many reasons, *see Summit* Reply 9, not least because *Neurontin* has been widely disapproved and stands in “disagreement with [at least] four circuits.” *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017). The majority position, held by at least the Second, Third, Seventh, Ninth, and Eleventh Circuits, is “that improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence.” *Id.* (collecting cases); *see also* Summit JM 11-17. The same result should be reached here, too, particularly given that the Hospital’s chain of causation is even more attenuated.

III. THE HOSPITAL’S SECTION 1962(A) AND SECTION 1962(D) RICO CLAIMS FAIL (COUNT 2).

The Hospital does not dispute that if its Section 1962(c) claim fails for lack of racketeering activity, an enterprise, or causation, its federal RICO claims under Sections 1962(a) and 1962(d) must be dismissed too. JM 6. The Opposition also makes clear that the Hospital cannot plead the *additional* elements required to state these claims.

A. The Hospital Has Not Alleged An “Investment Injury” Under Section 1962(a).

The Hospital does not dispute that it has failed to plead an investment injury that is “*distinct from* any injuries caused by the predicate acts of racketeering.” *Vemco, Inc. v. Camardella*, 23 F.3d 129, 132 (6th Cir. 1994) (emphasis in original); Opp. 26. Nor does the Hospital identify a single non-conclusory allegation to support any alleged investment injury. Opp. 27 (citing ¶ 892). Those failures are dispositive. JM 6-7.

The Hospital insists that it need “only” “allege an injury that is *traceable* to the investment of Defendants’ illegal gain,” even if it is the same injury caused by the “racketeering activity.” Opp. 26. This flatly contradicts binding precedent. The Sixth Circuit requires plaintiffs to plead “a separate *and* traceable injury” to state a claim under Section 1962(a). *Craighead v. E.F. Hutton & Co.*, 899 F.2d 485, 494 (6th Cir. 1990); *Vemco*, 23 F.3d at 132-33. Indeed, in *Vemco*, the Sixth Circuit affirmed dismissal of a Section 1962(a) claim precisely because the plaintiff failed to allege an injury “*separate from* the ‘predicate acts’ injuries.” *Vemco*, 23 F.3d at 133. Here too, the Hospital alleges that it was injured “through the above-referenced acts of racketeering.” Compl. ¶ 894. These allegations are not only entirely conclusory, but they “do not meet this Circuit’s requirement of a *distinct* ‘investment injury.’” *Vemco*, 23 F.3d at 133.

The Hospital’s interpretation of *Vemco* as not requiring plaintiffs to plead a distinct injury that is separate from injuries resulting from the alleged predicate acts, Opp. 26-27, would render *Vemco*—and the word “distinct”—meaningless. It also would eradicate the distinction between Section 1962(a) and Section 1962(c) liability. Indeed, since “corporations generally reinvest their profits, regardless of the source,” “[i]f plaintiff’s reinvestment injury concept were accepted, almost every pattern of racketeering activity by a corporation would be actionable under § 1962(a),

and the distinction between § 1962(a) and § 1962(c) would become meaningless.” *Brittingham v. Mobil Corp.*, 943 F.2d 297, 305 (3d Cir. 1991).

As support for its flawed reading of Section 1962(a) and controlling precedent, the Hospital relies entirely on *Vemco*’s distinction of an earlier case, *Newmyer v. Philatelic Leasing, Ltd.*, 888 F.2d 385 (6th Cir. 1989). Opp. 26. But, as the Sixth Circuit explained, *Newmyer* found that the plaintiffs sufficiently alleged a distinct investment injury where they had lost money in a fraudulent investment scheme funded by the proceeds of *prior* racketeering activity against *prior* alleged victims—that is, a distinct injury directly caused by the investment itself. *Vemco*, 23 F.3d at 133. In contrast, the plaintiff in *Vemco*—exactly like the Hospital here—alleged that racketeering income was subsequently used to operate the purported RICO enterprise, which, in turn, injured the plaintiff through the alleged predicate acts. *See id.*; Compl. ¶¶ 885-94. Under controlling law, the Hospital’s allegations do not and cannot state a claim under Section 1962(a).²

B. The Hospital Has Not Alleged A RICO Conspiracy Under Section 1962(d).

The Hospital’s RICO conspiracy claim is derivative and fails for the same reasons as its other RICO claims. JM 7; *Craighead*, 899 F.2d at 495 (“Plaintiffs’ [RICO] conspiracy claim cannot stand in light of the dismissal of their other RICO counts.”). The Hospital’s observation that “[a] conspiracy to commit a crime does not require that the crime be actually completed” changes nothing. Opp. 29 n.87. Regardless of whether an alleged crime was committed, the Hospital must still allege an illegal agreement involving the Manufacturer Defendants to commit a predicate *crime*. *See* 18 U.S.C. § 1962(d). Otherwise, the plaintiff has, at most, alleged an agreement to commit conduct that does not amount to a RICO violation. *See Craighead*, 899 F.2d

² The Hospital’s attempt to spin *Vemco* in its favor is further belied by its alternative request “to challenge the ruling in *Vemco*.” Opp. 27 n.85.

at 495 (affirming dismissal of § 1962(d) claim where plaintiff failed “to plead the existence of an agreement to engage in conduct that would amount to a RICO violation.”).

The conspiracy claim also fails because the Hospital has not adequately alleged a conspiratorial agreement. JM 7-8. The Hospital merely argues that the Manufacturer Defendants “engineer[ed]” the alleged “falsehoods outlined in the Complaint,” Opp. 30, without identifying any specific allegations regarding how or when that supposed collective “engineering” occurred—let alone identifying the existence of an actual agreement to engage in any mail or wire fraud (or any other predicate act). The Hospital’s argument and conclusory allegations fail to state a plausible conspiracy claim, and do not come close to meeting Rule 8(a)—let alone the particularity requirements of Rule 9(b). *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 553-554 (2007); *Huff v. FirstEnergy Corp.*, 972 F. Supp. 2d 1018, 1040 (N.D. Ohio 2013) (requiring plaintiff to specify “when, where, or between whom any alleged illicit agreement was made.”); *Craighead*, 899 F.2d at 495 (“[W]hile plaintiffs have pleaded the conclusory allegation that the defendants ‘conspired,’ they have failed to plead the elements of a conspiracy.”).

IV. THE HOSPITAL’S STATE LAW CLAIMS ARE PREEMPTED BY FEDERAL LAW (COUNTS 3-12).

The Hospital relies entirely on the preemption arguments set forth in *Summit* and *Broward*, Opp. 4-5, which effectively concede that state law claims based upon numerous legal theories are preempted by federal law. *Summit* Reply 11-13; *Broward* Reply 2. Likewise, for the same reasons explained by the Manufacturer Defendants in *Summit* and *Broward* as to why the remaining state law claims in those cases are preempted, any remaining state law claims asserted here cannot escape preemption. *Id.*

V. THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT CLAIM FAILS (“FDUTPA”) (COUNT 3).

A. The FDUTPA Claim Is Barred by the Safe-Harbor Provision.

The Hospital does not dispute that FDUTPA liability cannot be based on promotion consistent with FDA-approved product labeling. *See JM 9.* The Hospital nevertheless maintains that the safe harbor is inapplicable to claims premised on the various categories of alleged misrepresentations here (with no tie to any Hospital expense or prescription). Opp. 66 (citing Compl. ¶ 72). But each of these categories includes alleged misrepresentations that relate either to the safety and efficacy of opioid medications for the long-term treatment of chronic pain (*e.g.*, Compl. ¶ 72 (1)-(4)) or to the dosage and FDA-approved use of the medications (*e.g.*, *id.* ¶ 72 (5)-(7)).³ Because the FDA specifically approved extended-release opioid medications for treatment of chronic pain, the County’s FDUTPA claim fails, as it is based on advertising and promotion of these products consistent with that FDA-approved indication. *See JM 10.*

The Opposition fails to distinguish *Prohias v. Pfizer, Inc.*, where plaintiffs’ false advertising claims that attacked promotion consistent with the FDA-approved indication were “barred by the applicable state safe harbor statutes.” 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007). Plaintiff contends that the substance of the “statements made by Defendants was never approved or reviewed by the FDA.” Opp. 66. But in *Prohias*, the FDA had not approved the specific statements at issue; rather, the court found that “the alleged advertisements derive from, and largely comport with, the approved label.” 490 F. Supp. 2d at 1234. The same result follows here.

³ The other Paragraphs of the Complaint that the Hospital cites to show Defendants’ “fraudulent marketing scheme” do not contain allegations of any misrepresentation received and relied on by the Hospital. Opp. 66 n. 174 (citing Compl. ¶¶ 179-83, 288-99).

B. The Hospital Does Not Allege It Was Involved In A Consumer Transaction.

FDUTPA requires a consumer transaction, *see* JM 9-10; *Broward* Reply 6, yet the Hospital does not and cannot dispute that any unreimbursed costs of treating opioid-related conditions were not incurred in its capacity as a “consumer” of any medicine. JM 9. Likewise, the Hospital does not identify a single opioid prescription for which it purportedly paid and was not reimbursed by a patient or insurance—much less a single misrepresentation that induced those particular purchases. Opp. 9. The Hospital also does not dispute that, like a third-party payor, it purchased such medicines for patients, thereby acting only as an economic middleman. *Id.* at 9-10. Courts have dismissed similar claims against pharmaceutical manufacturers because economic middlemen are simply not “consumers.” JM 10 & n. 3 (collecting cases).

Nevertheless, the Hospital contends that any individual or entity may bring a FDUTPA claim. Opp. 61. The Hospital ignores that “the overwhelming weight of authority [is] in favor of a narrow reading . . . [that] FDUTPA applies only to a consumer injured by an unfair or deceptive act when buying or purchasing goods and services.” *Taft v. The Dade Cty. Bar Ass’n, Inc.*, 2015 WL 5771811, at *4 (S.D. Fla. 2015); *Gibson v. Resort at Paradise Lakes, LLC*, 2017 WL 3421532, at *5 (M.D. Fla. 2017). Because the Hospital does not allege facts showing that it was involved in a consumer transaction (let alone one that was fraudulently induced), its FDUTPA claims fail.

C. The Hospital Fails To Plead The Elements Of A FDUTPA Claim.

The Opposition fails to identify any false or misleading statements by any Manufacturer Defendant connected to any specific prescription, doctor, patient, or alleged harm to the Hospital. JM 10. Instead, the Opposition insists that it need not “identify any specific prescriptions for which it paid,” relying on an Ohio case where “*certain information [was] solely within the defendant’s knowledge.*” Opp. 61 (quoting *Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 630

(N.D. Ohio 2016) (emphasis in the Opposition). Even if FDUTPA recognized such an exception, the Hospital cannot point to any allegations showing that key information was solely within Manufacturer Defendants' knowledge; indeed, the Hospital not only alleges that the purported fraudulent statements were made publicly (including to doctors), but also fails to dispute that it knows what opioid prescriptions it paid for and why, whether they benefited patients, and what opioid-related services went unreimbursed. For this reason, courts have rejected the Hospital's very argument. *See, e.g., Travelers Indem. Co.*, 620 F. App'x at 87 n. 4 (affirming dismissal of similar claims and rejecting argument to relax pleading burden because "Defendants did not have exclusive control over significant information, such as the reasons that the doctors prescribed [the opioid medicines], or whether Plaintiffs' claimants who received those prescriptions benefitted from them").

In addition, the Hospital argues that it has pleaded a FDUTPA violation by establishing a violation of the Controlled Substances Act. Opp. 62. That argument fails for the reasons stated in *Broward* motion to dismiss briefing. *See Broward* Reply 6-7.

VI. THE MISLEADING ADVERTISING CLAIM FAILS (COUNT 4).

To plead a misleading advertising claim under Florida law, the Hospital must show, among other things, that *it* heard and relied on misrepresentations by the Manufacturer Defendants. JM 10-11. The Hospital contends that it has done so, Opp. 66-67 ("Defendants [must have] failed to read the allegations in the Plaintiff's Complaint"), but the cited examples (Compl. ¶¶ 178, 207, 436) are nothing more than recycled conclusory allegations⁴ about alleged statements made by unidentified individuals to unidentified doctors—not to the Hospital. There are certainly no

⁴ *See, e.g.*, Broward County SAC (MDL Dkt. 525) ¶¶ 165, 194, 408; Cabell County SAC (MDL Dkt. 518) ¶¶ 164, 193, 406; Monroe County SAC (MDL Dkt. 522) ¶¶ 158, 187, 401.

allegations that the Hospital relied upon any alleged statement or omission when reimbursing for opioid prescriptions or treating opioid-related conditions. Because there is no first-party reliance, the misleading advertising claim should be dismissed.

Presumably understanding this fundamental failure, the Hospital alternatively argues that reliance is not a required element of its claim. Opp. 67 n. 181. But in the very same breath, the Hospital admits it must establish that the suing “*party relied on some identifiable alleged misleading advertising* plus . . . all the other elements of the common law tort of fraud” Opp. 66. A plaintiff’s reasonable reliance on alleged fraud is an element of such a claim.⁵ The Hospital cites no case to the contrary.

VII. THE BREACH OF IMPLIED WARRANTY CLAIM FAILS (COUNT 5).

The Hospital does not respond to the Manufacturer Defendants’ arguments identifying the numerous deficiencies in the Hospital’s implied warranty claim. The Hospital has therefore abandoned this claim. *See Doe v. Bredesen*, 507 F.3d 998, 1007 (6th Cir. 2007) (“The district court correctly noted [] that Doe abandoned those claims by failing to raise them in his brief opposing the [] motion to dismiss”); *Ullmo v. Ohio Tpk. & Infrastructure Comm’n*, 126 F. Supp. 3d 910, 919 (N.D. Ohio 2015) (applying rule). Even were that not the case, any amendment would be futile because, among other things, the Manufacturer Defendants did not sell or market prescription opioid medications directly to the Hospital and the Hospital was using prescription

⁵ See, e.g., *Smith v. Mellon Bank*, 957 F.2d 856, 858 (11th Cir. 1992) (holding that “Florida law requires the plaintiff to prove reliance on the alleged misleading advertising”); *Samuels v. King Motor Co. of Fort Lauderdale*, 782 So.2d 489, 496 (Fla. Dist. Ct. App. 2001) (holding that defendant’s fraudulent intent must relate “to the misleading statement *made to the Plaintiffs*”); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1289 (S.D. Fla. 2009) (rejecting health fund’s misrepresentation and fraud claims because the fund failed to provide “any allegation relating to *any statement made directly to Plaintiff*, nor [] set forth any allegation of *how Plaintiff reasonably relied upon any statement made to it*”).

opioid medications for their ordinary purpose of providing pain relief. JM 27-29; *see SFS Check, LLC v. First Bank of Del.*, 774 F.3d 351, 355 (6th Cir. 2014) (“[C]ourts need not give leave to amend when doing so would be futile.”).

VIII. THE HOSPITAL’S NEGLIGENCE CLAIMS FAIL (COUNTS 6-10).

The Opposition does not meaningfully address the numerous deficiencies in the Hospital’s negligence claims, including that the Hospital fails to plead any actionable conduct, causation is lacking, the Hospital cannot use common law negligence theories under Florida law to circumvent the absence of a statutory cause of action under the Controlled Substances Act and other statutes, and the claims are preempted. JM 14-15. For each of these reasons, the negligence claims should be dismissed. The Opposition also confirms the additional reasons why these claims fail: no duty of care exists to the Hospital and Florida law does not recognize several claims. *Id.*

In an attempt to save its negligence claim, the Hospital asserts that, under Florida common law, a duty of care exists whenever harm is foreseeable. Opp. 40-42. But this is the rule in cases where a plaintiff’s harm was caused directly by the defendant, not a third party. *See Cook v. MillerCoors, LLC*, 829 F. Supp. 2d 1208, 1217 (M.D. Fla. 2011) (“[A]s a general principle, a party has no legal duty to control the conduct of a third person to prevent that person from causing harm to another.”). Here, the alleged injuries were not directly caused by the Manufacturer Defendants, but by various third parties further down the causation chain, such as “pill seekers” and others who abused opioids but cannot pay for medical care. Compl. ¶ 2. In such cases, Florida law will find a duty only if a defendant undertook “affirmative acts which create an unreasonable risk of harm by creating a foreseeable opportunity for third party criminal conduct.” *United States v. Stevens*, 994 So. 2d 1062, 1068 (Fla. 2008). The Hospital identifies no facts to show why the Manufacturer Defendants—by marketing and selling their lawful prescription medicines through a heavily-

regulated system involving the independent medical judgment of doctors—somehow created, much less should have foreseen, a risk of third-party criminal behavior (or any other behavior) that, in turn, would derivatively harm a hospital.

The Hospital primarily relies upon *Stevens*, a case that involved the anomalous and distinguishable duty of a government lab to implement appropriate security measures to protect “ultrahazardous” anthrax under its control. *Id.* Florida courts have found this ruling to be rooted in the “ultrahazardous” nature of handling anthrax, and have limited and distinguished *Stevens* because of its unique facts. *See Cook*, 829 F. Supp. 2d at 1217. The result in *Stevens* simply does not support finding a duty for pharmaceutical manufacturers to protect hospitals from the unreimbursed costs of treating injuries related to the consumption and diversion of FDA-approved medicines with significant therapeutic value—and labels with full risk disclosures—that can be lawfully dispensed only by licensed professionals obligated by law to know those risks.

Moreover, while the Hospital contends that it does not seek to enforce “statutory obligations concerning the administration and distribution of controlled substances,” Opp. 40, the Hospital argues that the alleged violation of these unidentified statutes establishes a *prima facie* claim of negligence. *Id.* at 42. Although Florida law allows statutory obligations to inform the relevant standard of reasonable care in certain instances, the Hospital must still plead and prove the existence and breach of a *duty*. *Kohl v. Kohl*, 149 So. 3d 127, 135 (Fla. Dist. Ct. App. 2014). Indeed, the very case that the Hospital relies on for this theory found that no duty existed *despite* proffered evidence of a statutory violation. *Id.*

Finally, the Hospital cannot save Counts IX (negligent marketing) and X (negligent distribution) of the Complaint because neither are recognized as independent causes of action under Florida law. JM 14. The cases that the Hospital cites, *see Opp.* 45-46, are all inapposite.⁶

IX. THE HOSPITAL’S PUBLIC NUISANCE CLAIM FAILS (COUNT 11).

The Hospital’s public nuisance claim fails for the same reasons stated in *Broward*, *Summit*, and *Cabell*, including that the Hospital cannot plead around Florida’s safe harbor for the sale of a lawful product; its injuries were not proximately caused by the Manufacturer Defendants’ alleged conduct; the alleged violations of law by the Manufacturer Defendants rest on a misunderstanding of their reporting obligations; and the allegations of fraud invoke individual, not public, rights. *See Summit* Reply 27-28 & n. 23, 32; *Broward* Reply 2-3; *Cabell* Reply 4. In response, the Hospital incorporates arguments from the opposition briefing in *Summit* and *Broward*. Opp. 31-32. Those arguments fail for the same reasons explained by the Manufacturer Defendants in their reply briefs in those cases. *Summit* Reply at 27-28; *Broward* Reply at 2-3.

In addition, without citing a single case, the Hospital speculates that proximate cause is not an element of a public nuisance claim under Florida common law. Opp. 38-39. The Hospital is wrong. JM 16. While the Hospital contends that “Defendants have not cited a single case” to the contrary, Opp. 38, *Penelas v. Arms Tech., Inc.* dismissed a public nuisance claim under Florida law against gun manufacturers and retailers because “a party cannot be held liable for nuisance

⁶ *See Godelia v. Doe*, 881 F.3d 1309, 1321 (11th Cir. 2018) (claim for fraudulent marketing, not negligent marketing); *Hunnings v. Texaco, Inc.*, 29 F.3d 1480, 1487 (11th Cir. 1994) (claim for general negligence, not negligent marketing); *Fisher v. Bumbo Int’l Tr.*, 2014 WL 12026083 (S.D. Fla. Aug. 20, 2014) (claim for strict products liability, with allegations of negligent marketing presented as evidence, not as separate cause of action); *Fagundez v. Louisville Ladder, Inc.*, 2011 WL 6754089, at *1 (S.D. Fla. Dec. 22, 2011), *report and recommendation adopted*, 2012 WL 12844303 (S.D. Fla. Jan. 19, 2012) (claim for strict products liability, with allegations of negligent distribution presented as evidence, not as separate cause of action); *Lewis v. City of Tallahassee*, 2006 WL 231291 at *3 (N.D. Fla. Jan. 30, 2006) (same).

absent control of the activity which creates the nuisance.” 1999 WL 1204353, at *4 (Fla. Cir. Ct. Dec. 13, 1999), *aff’d*, 778 So. 2d 1042 (Fla. Dist. Ct. App. 2001). That holding represents an application of proximate cause concepts to a specific, analogous context: criminal diversion and misuse of a lawful product. While the Hospital complains that *Penelas* is an “18-year old trial court decision,” Opp. 39, its rationale and holding are consistent with a long line of decisions from courts across the country dismissing similar public nuisance cases for lack of causation. *See Monroe* Reply 7-8; *Summit* Reply 27-28. Likewise, eliminating causation for public nuisance claims would raise serious constitutional concerns, and the Hospital fails to cite a single Florida case to support its radical departure from well-settled common-law principles. This claim fails.

X. THE HOSPITAL CANNOT SALVAGE ITS DEFECTIVE UNJUST ENRICHMENT CLAIM (COUNT 12).

The Hospital fails to allege that it conferred a direct benefit on the Manufacturer Defendants, as required to state an unjust enrichment claim. JM 17; *Broward* Reply at 7. The Opposition concedes that the Hospital cannot do so. Opp. 51-52. (“As purchasers, hospitals provide a financial benefit directly *to distributors*, and up the chain of distribution to the *manufacturers*. . . .”). Moreover, the Hospital does not dispute that it received the very opioid medicines for which it paid. This is fatal to its unjust enrichment claim.

The Hospital argues that a benefit is sufficiently direct even when passed through an intermediary, but the cases the Hospital cites are distinguishable because they generally involved plaintiffs who claimed they got a defective product, and, thus, did not receive the benefit for which they paid—unlike the Hospital, which received the exact, non-defective medications it purchased. Opp. 51-52 (citing *Melton v. Century Arms, Inc.*, 243 F. Supp. 3d 1290, 1307 (S.D. Fla. 2017) (defective rifles); *Carriuolo v. Gen. Motors LLC*, 72 F. Supp. 3d 1323, 1325-26 (S.D. Fla. 2014) (defective vehicle); *Feiner v. Innovation Ventures LLC*, 2013 WL 2386656, at *5 (S.D. Fla. May

20, 2013) (defective energy drink); *Romano v. Motorola, Inc.*, 2007 WL 4199781, at *2 (S.D. Fla. Nov. 26, 2007) (defective cell phone)).

Likewise, the Hospital argues that it conferred a benefit in the form of “ameliorating adverse conditions (sometimes referred to as ‘externalities’) created by the defendant’s conduct.” Opp. 53. But this theory has been rejected in Florida. *See City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1287-88 (11th Cir. 2015), *vacated and remanded, on other grounds, sub nom. Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296 (2017) (expressly rejecting the externalities theory, stating: “We have not found any case . . . supporting an unjust enrichment claim of this type under Florida law.”).⁷ Contrary to the Hospital’s contention, these legal flaws are not defects that can be cured through amendment, Opp. 57, and the Hospital fails to identify how it would do so. The Court therefore should dismiss the Hospital’s unjust enrichment claim with prejudice.

XI. ALL CLAIMS ARE TIME-BARRED IN PART.

Contrary to the Hospital’s position, Opp. 68, there is no question that the Hospital’s claims can be dismissed at this stage because its Complaint “shows on its face that the limitation period has run.” *Edward J. Goodman Life Income Tr. v. Jabil Circuit, Inc.*, 560 F. Supp. 2d 1221, 1229 (M.D. Fla. 2008); *see Bedtow Grp. II, LLC v. Ungerleider*, 684 F. App’x. 839, 841-42 (11th Cir. 2017). Indeed, the Sixth Circuit cases cited by the Hospital recite this same basic rule. Opp. 68; *Lutz v. Chesapeake Appalachia, L.L.C.*, 717 F.3d 459, 464 (6th Cir. 2013); *Am. Premier Underwriters, Inc. v. Nat’l R.R. Passenger Corp.*, 839 F.3d 458, 464 (6th Cir. 2016).

⁷ As in *Summit, Broward, Monroe, and Cabell*, the Opposition relies on non-binding cases such as *White v. Smith & Wesson Corp.*, 97 F. Supp. 2d. 816, 829 (N.D. Ohio 2000), *City of Los Angeles v. J.P. Morgan Chase & Co.*, 2014 WL 6453808, at *10 (C.D. Cal. Nov. 14, 2014), and *City of New York v. Lead Indus. Ass’n, Inc.*, 190 A.D.2d 173, 177 (N.Y. App. Div.). Applying Florida law, the Eleventh Circuit rejected all three cases and their underlying logic in *City of Miami*. 800 F.3d at 1288.

Based upon the allegations in the Complaint, the Hospital’s claims are time-barred and no exception applies. JM 17-20. Tellingly, the Opposition does *not* even address the merits of this argument. That is reason enough to dismiss the time-barred portions of its claims. To the extent the Hospital relies on arguments raised in the *Summit* and *Broward* briefs (despite asserting that its claims are “unique[],” Opp. 4, 35), the arguments fail for the same reasons as in those cases. *See Summit* JM 53-57; *Summit* Reply 36-38; *Broward* JM 17-20; *Broward* Reply 8-9.

XI. THE HOSPITAL’S REQUEST FOR PUNITIVE DAMAGES SHOULD BE STRICKEN.

The Hospital argues that it pleaded “detailed facts” in support of its punitive damages request, Opp. 69, but recites entirely conclusory allegations that fail to contain any alleged facts to support such a request. Opp. 69 & n.187 (citing Compl. ¶¶ 781-811). The Hospital also argues that it has alleged specific “deliberate,” “willful,” and “knowing” falsehoods elsewhere. *Id.* at 69 & n.188 (citing Compl. ¶¶ 155-465). The Hospital does not discuss these allegations (or link any such “falsehoods” to the Hospital or any particular injury it purportedly suffered), and the cited Paragraphs are simply the same deficient allegations that require dismissal of the substantive counts. These allegations neither support the request for punitive damages as to the Manufacturer Defendants, nor come close to pleading a “willful [sic] and wanton disregard for life equivalent to the standard required for proof of manslaughter,” as required to impose punitive damages under Florida law. *Keller Indus., Inc. v. Waters*, 501 So. 2d 125, 126 (Fla. Dist. Ct. App. 1987).

CONCLUSION

For the foregoing reasons, the Complaint should be dismissed. In addition, because the Hospital was given the opportunity to amend its Complaint, yet chose not to do so, and because the Hospital has failed to identify how it would purportedly cure the fundamental legal flaws in its Complaint, the dismissal should be with prejudice.

Dated: August 17, 2018

Respectfully submitted,

By: /s/ Steven A. Reed
Steven A. Reed
Eric W. Sitarchuk
Rebecca J. Hillyer
MORGAN, LEWIS & BOCKIUS LLP
1701 Market St.
Philadelphia, PA 19103-2921
Tel: (215) 963-5603
steven.reed@morganlewis.com
eric.sitarchuk@morganlewis.com
rebecca.hillyer@morganlewis.com

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131-2339
Tel: (305) 415-3000
brian.ercole@morganlewis.com

*Attorneys for Teva Pharmaceuticals, USA, Inc.,
Cephalon, Inc., Watson Laboratories, Inc., Actavis
LLC, and Actavis Pharma, Inc. f/k/a Watson
Pharma, Inc.*

By: /s/ Mark S. Cheffo (consent)
Mark S. Cheffo
Sheila L. Birnbaum
Hayden A. Coleman
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Mark.Cheffo@dechert.com
Sheila.Birnbaum@dechert.com
Hayden.Coleman@dechert.com

*Attorneys for Defendants Purdue Pharma L.P.,
Purdue Pharma Inc., and The Purdue Frederick
Company*

By: /s/ Charles C. Lifland (consent)

Charles C. Lifland
Sabrina H. Strong
O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071
Tel: (213) 430-6000
clifland@omm.com
sstrong@omm.com

Daniel M. Petrocelli
O'MELVENY & MYERS LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, CA 90067-6035
Tel: (310) 553-6700
dpetrocelli@omm.com

Attorneys for Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.

By: /s/ Jonathan L. Stern (consent)

Jonathan L. Stern
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave. NW
Washington, DC 20001
Tel: (202) 942-5000
jonathan.stern@arnoldporter.com

Sean O. Morris
Arnold & Porter Kaye Scholer LLP
777 S. Figueroa St., Suite 4400
Los Angeles, CA 90017
Tel: (213) 243-4000
sean.morris@arnoldporter.com

Attorneys for Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.

Attorneys for Defendants Par Pharmaceutical, Inc. and Par Pharmaceuticals Companies, Inc. (not yet served or appearing)

By: /s/ Brien T. O'Connor (consent)

Brien T. O'Connor
Andrew J. O'Connor
ROPES & GRAY LLP
Prudential Tower
800 Boylston St.
Boston, MA 02199-3600
Tel: (617) 235-4650
Brien.O'Connor@ropesgray.com
Andrew.O'Connor@ropesgray.com

Attorneys for Defendant Mallinckrodt LLC

By: /s/ Donna M. Welch (consent)

Donna M. Welch, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle, Chicago, IL 60654
Tel: (312) 862-2000
donna.welch@kirkland.com

*Attorney for Defendant Allergan Finance, LLC
f/k/a/ Actavis, Inc. f/k/a Watson Pharmaceuticals,
Inc.*

By: /s/ Eric H. Zagrans (consent)

Eric H. Zagrans (0013108)
ZAGRANS LAW FIRM LLC
6100 Oak Tree Boulevard, Suite 200
Cleveland, Ohio 44131
Tel: (216) 771-1000
eric@zagrans.com

J. Matthew Donohue
Joseph L. Franco
HOLLAND & KNIGHT LLP
2300 U.S. Bancorp Tower
111 S.W. Fifth Avenue
Portland, OR 97204
Tel: (503) 243-2300
matt.donohue@hklaw.com
joe.franco@hklaw.com

Nicholas A. Sarokhanian
HOLLAND & KNIGHT LLP
200 Crescent Court, Suite 1600
Dallas, TX 75201
Tel: 214.964.9500
nicholas.sarokhanian@hklaw.com

Attorneys for Insys Therapeutics, Inc.

LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the “litigation track” pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, and L.R. 7.1(f).

Dated: August 17 2018

By: /s/ Steven A. Reed
MORGAN, LEWIS & BOCKIUS LLP
1701 Market St.
Philadelphia, PA 19103-2921
Tel: (215) 963-5603

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2018, a copy of the foregoing **Reply in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Complaint** was filed electronically in MDL Master Docket No. 17-md-2804. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

By: /s/ Steven A. Reed
MORGAN, LEWIS & BOCKIUS LLP
1701 Market St.
Philadelphia, PA 19103-2921
Tel: (215) 963-5603